REMARKS

This Response is filed in connection with the non-final Office action mailed November 2, 2004. In the Office action, the Examiner stated that the Amendment and Response Under 37 C.F.R. § 1.116, filed in connection with the Request For Continued Examination (filed on August 11, 2004), has been entered. New claim 27 has been added to further clarify that which Applicants regard as the invention. Support for new claim 27 may be found, for example, in the specification as filed, on page 14, line 10 to page 18, line 34. Thus, claims 13-16, 26 and 27 are currently pending in the present application. No new matter has been introduced.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

The Examiner has maintained the rejection of claims 13-16 and 26 for lack of written description under 35 U.S.C. § 112, paragraph one, for the alleged failure of the disclosure to provide an adequate written description for the large genus of estrogen-regulated markers. In particular, the Examiner contends that there is a lack of written description for the claimed method for a genus of nucleic acids whose function is not known. Applicants respectfully assert that the requirements for written description under 35 U.S.C. § 112, paragraph one, have been fully satisfied; as such, the rejection should be withdrawn for the reasons detailed below.

Applicants respectfully remind the Examiner that the legal standard for the written description requirement under 35 U.S.C. § 112, paragraph one, has been set forth by the Court of Appeals for the Federal Circuit (see, *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d. 1306, 1319 (Fed. Cir. 2003); and *Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991)). To satisfy the requirement, an applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" (*Vas-Cath v. Mahurkar*, 935 F.2d at 1563-64; and Manual of Patent Examining Procedure, 8th ed., rev. 2, May 2004 ("MPEP") § 2163 at page 2100-164). Possession may be shown in a variety of ways, including description of an actual reduction to practice, or by any description of sufficient, relevant, identifying characteristics such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics (see *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002); and MPEP § 2163 at page 2100-171). For some biomolecules, examples of

identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length (emphasis added). See MPEP § 2163 at page 2100-171. Similarly, isolation of an mRNA and its expression to produce the protein of interest is "strong evidence of possession of an mRNA for the protein" (MPEP § 2163 at page 2100-171).

Applicants assert that the instant specification fully satisfies the written description requirement set forth by the Federal Circuit. Applicants respectfully remind the Examiner that the specification discloses the nucleotide sequence, *i.e.*, structure, of at least 75 examples of estrogen-regulated markers (ERMS) that may be used in accordance with the claimed assays (see, *e.g.*, Example 2 and Table I). Describing a nucleic acid by disclosing its nucleotide sequence, a sufficiently detailed, relevant identifying characteristic, fully satisfies the written description requirement for biological molecules as set forth by the Federal Circuit. The Examiner's citation to NCI-CGAP (accession number AA747315, 1999), which discloses a nucleotide sequence that is identical to the claimed sequence of SEQ ID NO:1 (formerly SEQ ID NO:57) in fact supports Applicants' present argument that disclosure of an identifying characteristic such as a nucleotide sequence fully satisfies the written description requirement, and that a further description of function is not required. Even so, Applicants have identified at least 75 examples of ERMs, including SEQ ID NO: 1, based upon experimental evidence that expression of these markers is regulated in response to modulation of the estrogen receptor (see Example 2 and Table I of the present specification), thereby providing both structural and functional support for the identified ERM sequences.

Further, the written description requirement for a claimed genus may also be satisfied through sufficient description of a number of species by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical, chemical and/or functional properties, sufficient to show the applicant was in possession of the claimed genus (see *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("*Eli Lilly*") and MPEP § 2163 at 2100-174). In *Eli Lilly*, the Federal Circuit emphasized that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (emphasis added). *Eli Lilly*, 119 F.3d at 1569. Thus, *Eli Lilly* makes it clear that although function alone may not sufficient to describe a claimed genus, the nucleotide sequence of each of the individual species of a genus is adequate for purposes of satisfying the written description requirement

under 35 U.S.C. § 112, paragraph one. In the presently claimed invention, the written description requirement for the claimed genus (*i.e.*, estrogen-related markers ("ERMs") responsive to estrogen and/or a candidate selective estrogen receptor modulator ("SERM")) has been sufficiently satisfied through sufficient description of a representative number of species (*i.e.*, by disclosing the nucleotide sequences of at least 75 ERMs that are modulated by estrogen and/or a candidate SERM). Such a description is clearly sufficient to show that Applicants were in possession of the claimed genus at the time the application was filed.

For the forgoing reasons, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, of claims 13-16 and 26 be withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

The Examiner has maintained the rejections of claims 13-16 and 26, which are drawn to methods for identifying a SERM, as being anticipated by Mendelsohn *et al.* (United States Patent No. 5,728,534, dated Mar. 17, 1998) ("Mendelsohn"). Applicants respectfully submit that the Examiner has mischaracterized Mendelsohn. In particular, the Examiner contends that Mendelsohn teaches the screening assays of the instant invention, and thereby anticipates the claims. This rejection is in error for the reasons detailed below and should be withdrawn.

Applicants respectfully remind the Examiner that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (see, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the...claim" (see, *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)). Applicants point out that the Mendelsohn reference does not satisfy the requirements for anticipation as set forth by the Federal Circuit.

In brief, the present invention relates to an assay for the identification of a SERM, a selective estrogen-responsive modulator, whereby the assay comprises contacting cells expressing an estrogen-regulated marker(s) (ERM) with estrogen or a test agent, and determining the expression of at least one endogenously-expressed ERM in the cells and comparing the levels of expression in the presence and the absence of the test agent, and therefrom determining whether the test agent is a SERM. A difference in expression levels of the endogenously-expressed ERM relative to a control indicates that the test agent is a SERM (*see* Example 4). Such expression can be determined by any number of assays available to those skilled in the art that quantitatively measure the level of mRNA or protein, *e.g.*, RNAse

protection assays, Western blot or ELISA (see, *e.g.*, page 14, line 19 to page 18, line 34, and Example 4 of the specification as filed).

In contrast, the assays described in Mendelsohn are for the identification of vasoprotective agents based on the ability of a test agent with known estrogen receptor inductive effects to selectively induce the activity of a non-native reporter construct containing an upstream regulatory region of an estrogen receptor responsive gene, or an isolated estrogen receptor recognition element (ERE) operably linked to a nucleotide sequence encoding a detectable protein, *e.g.*, luciferase (*see* Mendelsohn, col. 11, lines 11-36). In contrast to the presently claimed invention, Mendelsohn does not teach determining the expression levels of an endogenously expressed ERM in response to treatment of estrogen or a candidate SERM, for example, using an RNAse protection assay, Western blot or ELISA. Thus, Mendelsohn is clearly distinguishable from Applicants' presently claimed invention.

In summary, Mendelsohn does not set forth "each and every element as set forth in the claim[s]." As such, the Mendelsohn reference cannot form the proper basis of a rejection of the present claims under 35 U.S.C. § 102(b).

Applicants respectfully request that, for the forgoing reasons, the anticipation rejection of claims 13-16 and 26 be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks intended to put the claims in form for allowance. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned at (212) 326-3939, if a telephone call could help resolve any remaining items.

Respectfully submitted, by Jacqueline Benn
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